

## **REMARKS**

The Office is respectfully requested to reexamine and allow claims 1-64 in the present merged reissue application and reexamination proceeding. The patent owner respectfully traverses the rejections of record and requests that they be withdrawn, in view of this response.

### **Claim Amendments, Status, and Support**

Claims 1-64 are pending. A complete set of claims is attached as an appendix.

Claims 18 and 53 have been amended, as shown above, to recite a dilatation balloon as element c and in the preamble. This is disclosed, for example, at claim 1 of the original patent, originally filed in the application as claim 5.

### **No Recapture**

The applicant respectfully traverses the rejection of claims 18-64 on the basis of recapture. The claims do not recapture subject matter given up to avoid the prior art in original prosecution.

The first step in a recapture analysis is to determine what subject matter was given up in the last amendment to avoid the prior art, before the claims were allowed.

Comparing application claim 1 as originally filed to claim 5 as presented in Amendment A filed August 24, 1995, (claim 1 as granted), no change was made in the recited physical properties. Application claim 1 as originally filed required, "a tensile strength greater than about 10,000 psi, an elongation greater than about 50% and a tensile modulus greater than about 300,000 psi." Application claim 5, granted as patent claim 1, also required, "a tensile strength greater than 10,000 psi, an elongation greater than 50% and a tensile modulus greater than 300,000 psi." No claim scope was given up respecting these three physical properties between claim 1 as originally filed and claim 5 as amended. Thus, a broader claim omitting or changing these properties does not represent recapture.

The Examiner is correct that application claim 1 as originally filed does not recite a balloon, while claim 5 as presented in Amendment A filed August 24, 1995, (claim 1

as granted after further amendments to address Section 112 issues) does recite a dilatation balloon. This amendment was submitted after a rejection based on the Hamlin prior art. But this amendment was not made to avoid the Hamlin prior art. The Hamlin prior art, U.S. Patent No. 5,270,086, was itself directed to a balloon dilatation catheter, so canceling application claim 1 that did not recite a balloon dilatation catheter, while maintaining claim 5 that did recite a balloon dilatation catheter, is not a concession of subject matter to avoid the prior art. Since no subject matter was conceded during original prosecution to avoid the prior art, omitting the limitation of a balloon now does not recapture any conceded subject matter.

Respecting claims 18, 53, and 57, the Examiner is correct that these claims are broader than original patent claim 1, as each of claims 18, 53, and 57 omits one or more of the requirements of "a tensile strength greater than 10,000 psi, an elongation greater than 50% and a tensile modulus greater than 300,000 psi," and each of these claims omits the requirement for a dilatation balloon, compared to application claim 1 as originally presented. That is why this is a broadening reissue application. But none of these differences are prohibited by the rule against recaptured subject matter, as explained above.

Finally, canceled application claim 1 recites a modulus of "greater than 300,000 psi," while claim 57 recites a modulus of "greater than 400,000 psi," But this means claim 57 is narrower than application claim 1, not broader. For example, application claim 1 embraces a modulus of 350,000 psi, while newly presented claim 57 does not literally cover a modulus of 350,000 psi. Claim 57 is thus narrower, not broader, in this respect.

For the stated reasons, the claims do not represent prohibited recapture because they do not attempt to recapture subject matter given up to avoid the prior art.

## **Novelty**

Claims 18-22, 26, 27, 31-48, and 51-64 are rejected on the basis of anticipation or alternatively obviousness, respecting Biesel, with reference to Muni and Bennett. The applicant understands that the anticipation ground is based on Biesel alone. The Beisel reference, page 7 refers to a PEEK tensile strength of  $13.6 \times 10^3$  psi, which is 13,600 psi.

Present claims 18-56 recite a dilatation balloon, which Beisel does not disclose. Therefore, claims 18-22, 26, 27, 31-48, and 51-56 are novel.

Present claims 57-64 recite an elongation of greater than 50%, which the Beisel reference fails to disclose. Therefore, these claims are novel. The recited elongation is called "modest" in the Office action, but is not inherent in the recited reference.

The Examiner correctly points out that the Muni and Beisel references fail to disclose the elongation at break of the materials employed in those references. The only applied reference that mentions elongation at break is the Bennett reference. Thus, only the Bennett reference contains tensile, modulus, and elongation information for the same material samples. These properties should be considered together, as they are interrelated and vary with material processing conditions. As the Reexamination Requester asserted, on page 5 of the Request for Reexamination filed March 23, 1998 (with the underline added here):

It is axiomatic that the tensile strength, tensile modulus and elongation properties, as recited in the claims of Ainsworth '121, are all dependent on the crystallinity of the extruded material. Ainsworth et al. admit in their response during [the prior Ainsworth '121] Reexam that it is the crystallinity that they alter during extrusion. Crystallinity stiffens the material, and a stiffer material provides a higher tensile strength, a higher tensile modulus, and a lower elongation."

In other words, increasing crystallinity has both good and bad effects, in terms of the present invention – it provides a high tensile strength and modulus, which are

desirable here within certain ranges, but it provides a lower elongation, which is undesirable here. No evidence is shown that the high elongation (greater than 50%) is inherent in the recited materials having a tensile modulus greater than 400,000 psi. Therefore the claims are novel in view of the applied prior art.

### **All Pending Claims (35 USC 103)**

All the pending claims should be allowed over the prior art of record because none of the prior art, individually or combined, takes into account the relation of the shaft dimensions and function of the catheter to the needed mechanical properties of the shaft. The Beisel reference indicates that its epidural catheters should be about 91.4 cm or 36 inches long. See page 5, lines 29-30. The mechanical properties it mentions are for a catheter of that length adapted for epidural insertion, which does not appear to involve threading the catheter through tortuous anatomy. Once the catheter enters the epidural space, the catheter is simply inserted into and through that space. Beisel, page 1, lines 21-23.

The specification of the Ainsworth '121 patent under reexamination/reissue indicates that the present angioplasty catheters (see Col. 1, lines 6-8) are much longer – about 120 to 150 cm in length (Col. 3, lines 14-16). Catheters according to the present invention serve a different purpose than epidural catheters. In particular, an angioplasty catheter 10 illustrated in the Figures of the present patent must be able to flex sufficiently to follow a tortuous path dictated by a guidewire 18 guiding the catheter through tortuous vascular passages (Col. 1, lines 45-46). The substantial length of these passages dictates a longer catheter, and increases the need for stiffness in the proximal shaft so the longer catheter will not buckle when pushed from the proximal end through tortuous anatomy encountered at its distal end.

Because the catheters of Beisel and the present patented invention are very different, it would not be obvious to provide material having the properties recited in the Beisel reference for use in the angioplasty catheters of the present invention. Given that the properties of PEEK and other engineering thermoplastics can be deliberately modified by processing, one skilled in the art cannot merely select a material to use, but

must select the properties needed of the extruded material and be aware that one can process that material as needed to get the properties required for the end use.

**Additional Comments Regarding  
Claims 4, 15, 36, 41-42, and 57-64 (35 USC 103)**

The present rejections of at least claims 4, 15, 36, 41-42, and 57-64 should also be withdrawn for the following reasons.

First, as mentioned above, the Examiner correctly points out that the Muni and Beisel references fail to disclose the elongation at break of the materials employed in those references. Similarly, the Cornelius reference fails to disclose any of the claimed properties. The only applied reference that mentions elongation at break is the Bennett reference. Thus, only the Bennett reference contains tensile, modulus, and elongation information for the same material samples. The question becomes whether it would be obvious to modify the processing of the Bennett materials to achieve all the properties required by the present claims 4, 15, 41-42, and 57-64.

But if one increases crystallinity, to increase the tensile modulus above 400,000, damage is done to the elongation of the more-crystalline material. In already-stiff materials, in an application where flexibility remains essential (e.g. the vascular catheters of the present invention), it would not be obvious to increase the modulus at the expense of elongation. See the present (Ainsworth '121) patent, col. 2, lines 26-32, which indicates the importance of high elongation properties to prevent kinking. No reason is shown why a person of merely ordinary skill in the art would expect to raise the crystallinity high enough to increase the tensile modulus above 400,000, without degrading the elongation properties undesirably.

Second, claims 15, 36, and 41-42 are limited to a PEEK catheter shaft having a tensile strength of at least 14,000 psi, which is 97 MPa, using the conversion factor (145 psi = 1 MPa) provided on page 15 of the Reexamination Request. The Bennett and Beisel references – the only ones disclosing the tensile strength of PEEK – do not disclose any PEEK test materials that have a tensile strength this high.

Example 2 of Bennett, for example, shows a PEEK material having a tensile strength at break of 88 MPa, or 12,600 psi. Examples 1, 3-4, 6, 8, 10-15, and 17-22 of Bennett relate only to PEEKK, which is a different material. See Bennett, col. 1, lines 29-36 and col. 2, lines 10-15. No reason is disclosed in this reference for assuming that the tensile strength of PEEK can be increased over 14,000 psi, absent any disclosure of that tensile strength in the cited prior art.

Table I on page 7 of Beisel discloses a tensile strength for PEEK of just 93.8 MPa (13,600 psi), which also is less than 14,000. No reason is disclosed in this reference for assuming that the tensile strength of PEEK can be increased over 14,000 psi, absent any disclosure of that tensile strength in the cited prior art.

Claims 4, 15, 36, 41-42, and 57-64, therefore, should be patented because they are not disclosed or obvious in view of the prior art, including the Beisel and/or Bennett references.

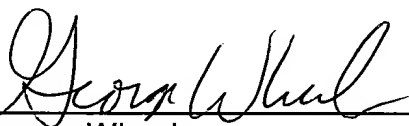
## **Conclusion**

For the reasons stated above, claims 1-64 should be allowed.

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Respectfully submitted,

  
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